

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

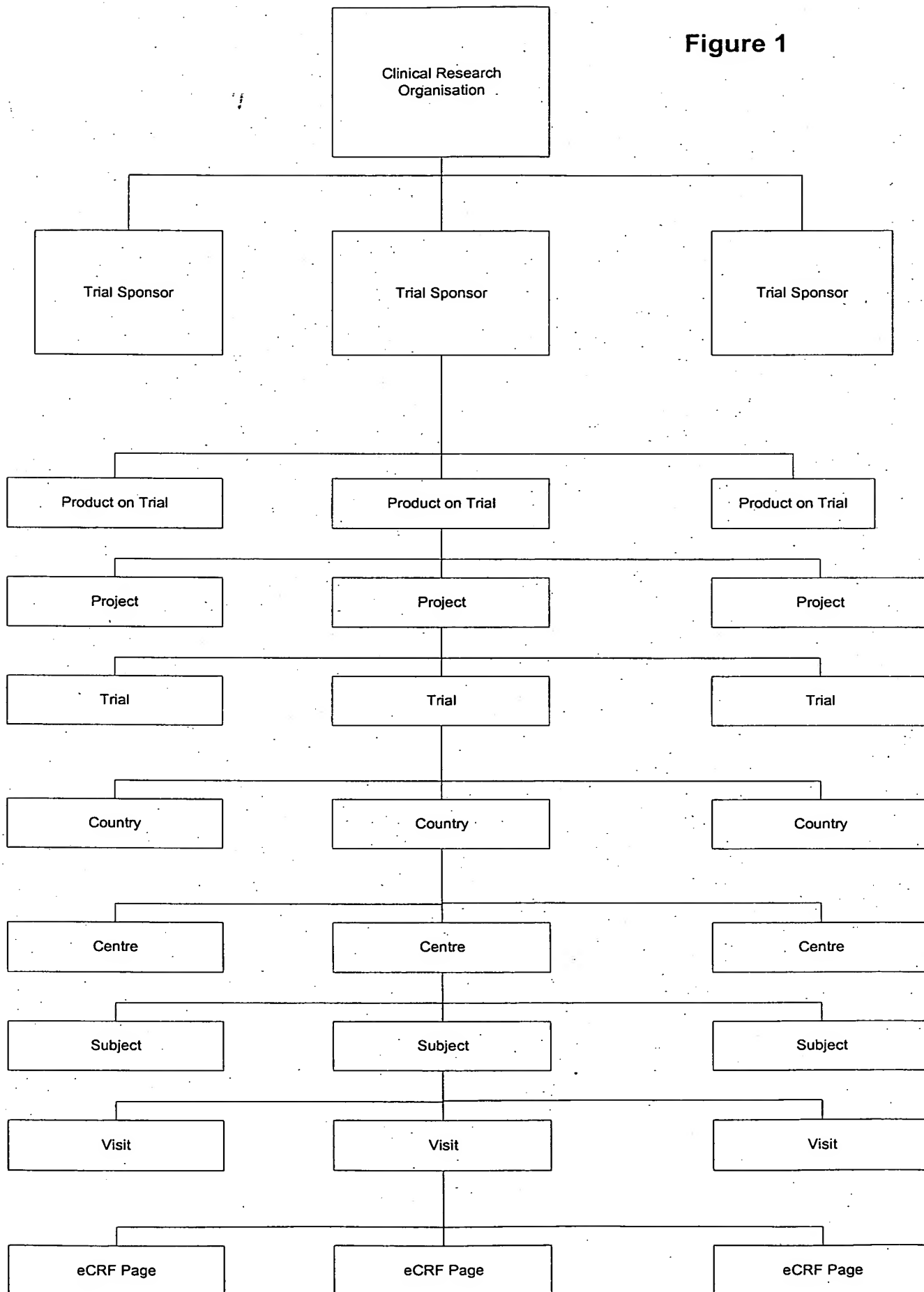
Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

Figure 1



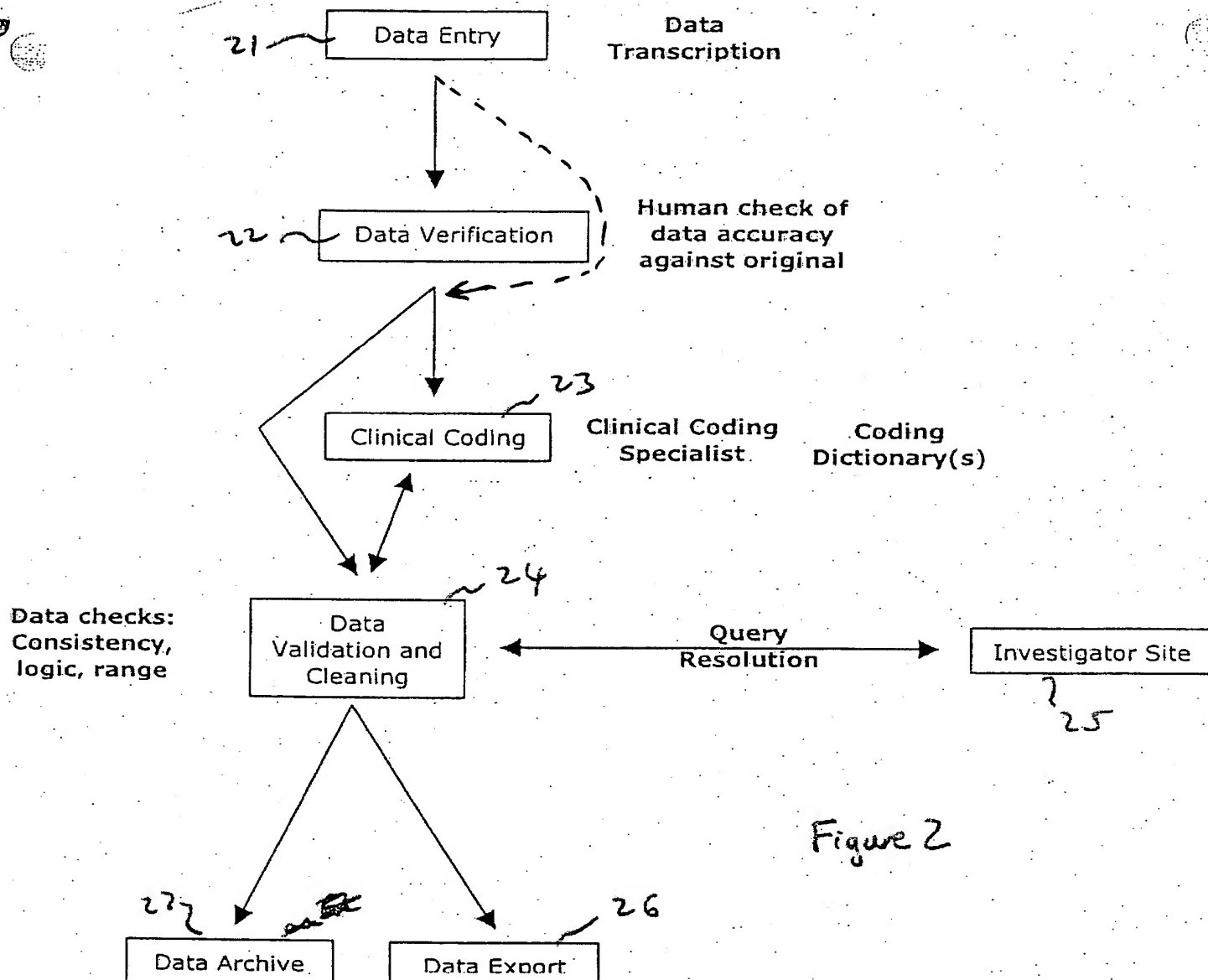


Figure 3

40

User: Tim Role: Design Home

Subject: GFG 23111945/54 Visit: First Visit Page: #

Page submitted by: Tim with Design role at 15:52:02 on Tue May 15 2001

History: Page

CRO Any CRO Name
Sponsor Any Pharmaceutical Name
Product COPD New Drug
Project Primary Indication
Trial Phase III No. 1
Country England
Centre East Anglia No.1
Subject GFG 23111945/54
Visit First Visit
Page History

Context:
CRO Any CRO Name
Sponsor Any Pharmaceutical Name
Product COPD New Drug
Project Primary Indication
Trial Phase III No. 1
Country England
Centre East Anglia No.1
Subject GFG 23111945/54
Visit First Visit
Page History

Audit Trail:
Version 1 of 1 Prev Next Delete

Workflow:
Clinical: PV, VI, Err, OK, NA, OK
Coding: Err, U, G, NA, AOK, OK
Reporting: Up, Prev, AutoPrev
Ready Down Next AutoNext

Please list any significant medical history/concomitant diseases (not related to trial indication)
History or diagnosis (Enter only one per field. Use precise medical terminology. If none enter none)
Date of diagnosis/surgery (day month year)
Active problem? (Circle appropriate code)

Submit

246

44

48

42

Local time Tue May 15 15:52:37:2001 BST
UTC time Tue May 15 14:52:37:2001

DEBUG Update



Figure 5

Figure 4

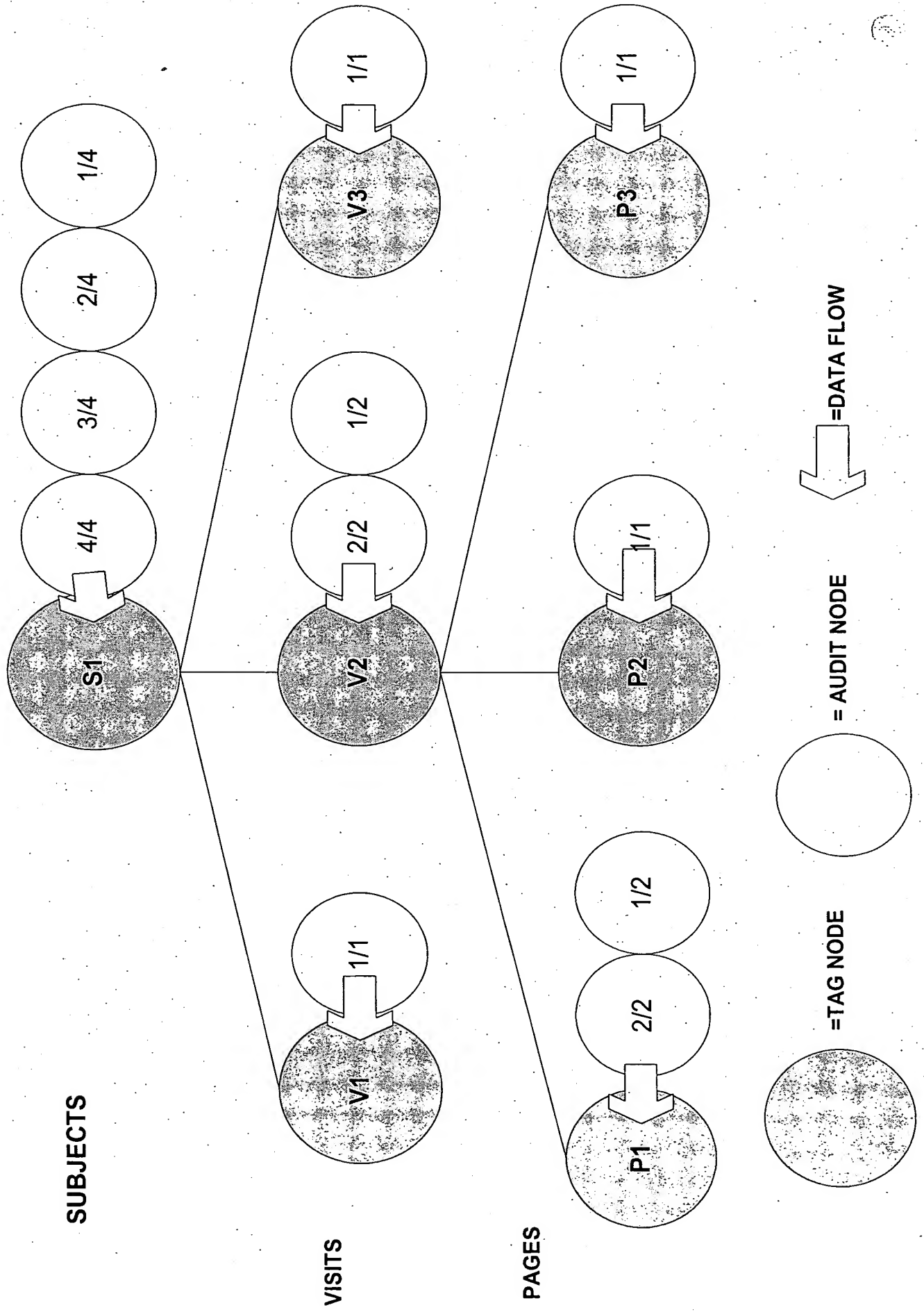


Figure 6

ian Davey (tp.dev3-d4) Validation

History: Back Forward

Level Context

trial "phase 111 no. 1"

User: tp.dev3-d4800 UTC date: 10 May 2002
Role: Design UTC time: 09:23:40

root

cro Validation Trial (ID-MH-2002 DE 100
sponsor pharma company 1
product new drug 1
project primary indication 1
trial phase 111 no. 1 1

Filtered Sublevels

Clinicals References Deleted

Queries Searches Reports

VI Err Q NA OK
cErr cu ci cNA cAOK cIOK

type name
country uk
country usa

Help

Live Report trial "phase 111 no. 1"

Level Totals

CRO: 0 Country: 2 Ongoing: 8
Sponsor: 0 Centre: 4 Page: 124
Product: 0 Subject: 8 User: 1
Project: 0 Cycle: 8 Script: 0
Trial: 0 Visit: 25 Export: 1

Clinical Flag Totals

NE - 0
PV - 0
Err - 0 VI - 0
Q - 0
OK - 0 NA - 0

State Totals

Cycle: 8
Ongoing Visit: 25
Page: 124

Received Entered

Coding Flag Totals

CU - 0
CI - 0 cErr - 0
CAOK - 0 cIOK - 0
CNA - 0

Issues